Amend claim 28 as follows:

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28. (Twice amended) An introducer as in claim 27 wherein the long flexible extension includes a hollow tube therethrough in fluid communication with the flexible thin walled tube and a plurality of side holes to enable dispersion of the medical reagent proximal of the prosthesis.

Remarks

In the Office action of April 24, 2002, Paper No. 8, claims 1-63 are pending in the application of which claims 12-17 and 43-63 are withdrawn from consideration. Claims 1-11 and 18-42 are rejected, and claims 5-8 and 18-23 are objected to. The drawing was objected to by the Examiner. Acknowledgment was made of a claim for foreign priority under 35 U.S.C. 119(a)-(d) or (f). None of the certified copies of the priority documents have been received. Accordingly, enclosed is a certified copy of International Application PCT/AU98/00383 as filed at the Australian Receiving Office on May 25, 1998 and a certified copy of Australian Provisional Application No. PO 7008 filed May 26, 1997. In particular, claims 14, 15 and 17 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected species. Also claims 18-23 which depend on claims 14-17 were withdrawn from further consideration as being drawn to a non-elected species. The drawings were objected to as failing to comply with 37 CFR 1.84(p)(4) because the reference character "23" has been used to designate both the aperture in Fig. 9 and a portion of trigger wire in Fig. 8. A proposed drawing correction was required in reply to the Office Action to avoid abandonment of the application. Accordingly, a copy of Fig. 8 is enclosed with a red-inked correction changing character "23" to character "22." In addition, the leader line from character "15" has been crossed out and reinserted to the proper tubular component. Approval of this correction is requested.

The drawing was also objected to as failing to comply with 37 CFR 1.84(p)(5), because it does not include the reference character "19" found on page 14, line 15. In response, the Examiner's attention is directed to the cited text and, in particular, the paragraph bridging pages 13 and 14 and the subsequent paragraph on page 14 including cited line 15. As can be seen from these two paragraphs, the text is directed to Fig. 9 in which character "19" is readily found in the upper left-hand corner thereof indicating a resilient stent. Accordingly, applicant requests that the objection to Fig. 9 of the drawing be withdrawn. However, for sake of completeness, "longitudinal aperture 12" found in these two paragraphs is now also being included in Fig. 9 with character "12" and its leader line being included in red ink. Furthermore, a red-inked, dashed connecting line has also been submitted to interconnect the two portions of the apparatus depicted in Fig. 9. Approval of these red-inked corrections is requested.

Also in the particulars of the Office Action, claims 18 and 23 were objected to because of minor informalities. Claims 5-8 and 19-23 depending on respective claims 4-7 and 18-22 were objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. By this amendment, dependent claims 4, 8, and 18-23 are being amended to correct the multiple dependent claim problem noted by the Examiner. Furthermore, claims 18 and 23 are being amended to correct the minor informalities noted by the Examiner. In view thereof, applicants submit that claims 18 and 23, as amended herein, correct the minor informalities noted by the Examiner, and it is requested that the objections to these claims be withdrawn. Furthermore, since claims 4, 8, and 18-23 have been amended to correct the multiple dependency problem, it is requested that the objection to claims 8 and 19-23, as amended herein, and claims 5-7 be withdrawn and that they be further examined on the merits.

Also in the Office Action, claims 27 and 28 were rejected under 35 U.S.C 112, second paragraph, for insufficient antecedent basis. Claims 27 and 28 have been amended to correct the antecedent basis problem, and it is requested

that the rejection of these claims under 35 U.S.C. 112, second paragraph, be withdrawn.

Claims 1-11 and 18-42 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant traverses this rejection. First, the Examiner indicated that the specification failed to disclose how to make or use control members for introducing or controlling the position of the proximal or distal portions of a prosthesis. In the originally submitted claims and, in particular claim 1, the first control member was parenthetically indicated as including elements 22 and 24; whereas the second control member was parenthetically identified as including elements 44 and 25. The Examiner's attention is directed to page 14, lines 15-24 in which element 22 is identified as trigger wire 22, and element 24 is identified as proximal wire release mechanism 24. This trigger wire is also disclosed as retaining zigzag stent 21 in cylindrical sleeve 10 of the proximal attachment region 3 by extending through aperture 23 in the side of the proximal attachment device 10 and in one of the loops of the zigzag stent. The trigger wire extends along the length of the introducer and exits at the manipulation region at a proximal wire release mechanism 24. Thus, it should be evident to anyone skilled in the art that the trigger wire 22 and proximal wire release mechanism 24 control the proximal portion of the prosthesis and, in particular, the proximal zigzag stent retained in cylindrical sleeve 10 of the proximal attachment region 3.

Likewise, the Examiner's attention is directed to page 15, lines 1-8, in which element 44 is identified as distal trigger wire 44, and element 25 is identified as distal wire release mechanism 25. On page 17, lines 26-32, distal end 42 of the prosthesis is released by the removal of distal trigger wire 44. Distal wire release mechanism 25 and distal trigger wire 44 can be completely removed from the introducer. Thus, loop 43 of the terminal distal zigzag stent is free. Thus, anyone skilled in the art would see how the distal trigger wire 44 controls positioning of the distal portion of the prosthesis and, in particular, the distal zigzag stent.

This interaction is further supported by Figs. 3-5, 8 and 9 in which proximal trigger 22 wire extends through a loop of the proximal zigzag stent of the prosthesis, and distal trigger wire 44 extends through loop 43 of distal zigzag stent of the prosthesis. The inner connection of the distal and proximal trigger wires also addresses the second item noted by the Examiner in which the Examiner questions how the trigger wires are secured to the prosthesis through the distal end portion of the introducer or sleeve 10.

The Examiner also questions how the trigger wires are detached from the introducer in order to position the distal and proximal portions of the prosthesis at a desired site in a body lumen. The Examiner's attention is again drawn to page 17, lines 5-32, in which the proximal and distal trigger wires 22 and 44 along with their respective proximal and distal wire release mechanisms 24 and 25 can be completely removed from the introducer by sliding the proximal and distal wire release mechanisms 24 and 25 over pin vice 39, 46 thus completely removing the trigger wires and release mechanisms from the introducer. Such removal allows the proximal and distal end stents to be released at a desired site in a body lumen.

In view of the above, applicant submits that the specification enables anyone skilled in the art to make and/use the claimed invention. Accordingly, applicant submits that there is a sufficient enabling disclosure, and it is requested that the rejection of claims 1, 4, 8, 9, 18-24, 27 and 28, as amended herein, and claims 2, 3, 5-7, 10, 11, 25, 26, and 29-42 under 35 U.S.C. 112, first paragraph, as containing subject matter which is not disclosed in the specification, be withdrawn.

By this amendment, independent claims 1, 9 and 24 have been amended to overcome the rejection under 35 U.S.C. 102(e) and, in particular, to distinguish over Quiachon (783). In particular, independent claim 1, as amended herein, includes a first control member that is separable from the prosthesis positioning mechanism, retains the prosthesis positioning mechanism with the proximal portion of the prosthesis and controls at least the longitudinal position of the proximal portion of the prosthesis. For the purpose of discussion herein, the Examiner's attention is directed to the fact that applicant's designation of "proximal" and

"distal" are opposite in position to that designated in Quiachon. As disclosed in Quiachon and, in particular Figs. 1, 4 and 8, and column 11, lines 20-42, a control wire 91 is attached to distal capsule assembly 90 and is fixedly attached thereto by a U-shaped bend through the distal cap insert. Thus, control wire 91 is not separable from the prosthesis positioning mechanism as in applicant's claimed invention in independent claim 1, as amended herein. Furthermore, as depicted in Fig. 8 of Quiachon, there is no locking wire or control member retaining the prosthesis and, in particular, spring 175 to distal capsule assembly 90. As depicted in Figs. 1, 7 and 8 and described in column 20, line 39 to column 22, line 64, of Quiachon, a distal locking ball 208 and a proximal locking ball 209 are fixed at the end of pull wire 207 and are used to retain inferior attachment system 176 secured to contralateral tubular leg 172 in contralateral capsule 202. As depicted in Figs. 1, 3 and 8 and described in columns 10 and 11, lines 53-8, locking rings 86 and 87 are attached to ipsilateral locking wire 85 to retain inferior attachment system 176 that is secured to ipsilateral tubular leg 171 in proximal capsule 132. However, a locking wire or retention system is not provided for superior attachment system 175 and distal capsule 93. With the inferior ends of the graft held in place by the inferior attachment systems retained in the proximal capsules, the distal capsule 93 is simply advanced forward to release superior attachment system or spring 175 therefrom. The longitudinal position of the graft is maintained by the inferior attachment systems retained in the proximal capsules.

The Quiachon introducer does not disclose a first control member that is separable from the prosthesis positioning mechanism and also retains the prosthesis positioning mechanism with a proximal portion of the prosthesis. Since Quiachon does not identically disclose a first control member that is separable from the prosthesis positioning member and retains the prosthesis positioning mechanism with the prosthesis, Quiachon does not anticipate independent claim 1, as amended herein, and it is requested that the rejection of claims 1, 4 and 8, as amended herein, and claims 2, 3 and 5-7 under 35 U.S.C. 102(e) as being anticipated by Quiachon, be withdrawn.

Independent claim 9, as amended herein, is directed to an endovascular arrangement wherein a first member extends from the control section to a proximal region of the positioning mechanism and controls the longitudinal and rotational position of the proximal region of the positioning mechanism. Furthermore, the arrangement includes a second member that extends from the control section to a distal region of the positioning mechanism and independent of the first member controls the longitudinal and rotational position of the distal region of the positioning mechanism. The Examiner's attention is directed to column 11, lines 45-47, wherein the U-shaped bend of the control wire through the distal cap insert prevents the distal cap assembly from rotating in relation to the balloon catheter shaft. Accordingly, Quiachon does not identically disclose an endovascular arrangement including a first member that controls the longitudinal and rotational position of the proximal region of the positioning mechanism as claimed in applicant's independent claim 9, as amended herein. Thus, applicant's request that the rejection of claims 9 and 18-23, as amended herein, and dependent claims 10 and 11 under 35 U.S.C. 102(e) as being anticipated by Quiachon, be withdrawn.

Independent claim 24, as amended herein, is directed to an introducer including proximal and distal attachment devices that are adapted to be attached to respective proximal and distal ends of a prosthesis. Each of the proximal and distal attachment devices are attached to the prosthesis so that each end of the prosthesis can individually be moved in proximal and distal directions and be rotated "independent of the other." Furthermore, the introducer includes proximal releasing means associated with and separable from the proximal attachment device and distal releasing means associated with and separable from the distal attachment device to enable selective releasing of the proximal and distal ends of the prosthesis. As previously discussed, Quiachon does not have a proximal attachment device that can be rotated as previously indicated. Furthermore, Quiachon does not have proximal releasing means that is separable from the proximal attachment device to enable selective release of the proximal end of the prosthesis. The Examiner is again reminded that the proximal designation utilized in applicants claims refers to the distal end of the introducer in Quiachon. In view

thereof, Quiachon does not identically disclose an introducer as claimed in independent claim 24, as amended herein, and it is requested that the rejection of claims 24, 27 and 28, as amended herein, and dependent claims 25, 26 and 30-42 under 35 U.S.C. 102(e) as being anticipated by Quiachon, be withdrawn.

Enclosed is a petition and fee for extension of time (two months)

The reexamination and reconsideration of this application is respectfully requested, and it is further requested that the application be passed to issue.

Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment.

Respectfully submitted,

David Hartley
Michael Lawrence Brown

Date: Sept. 24, 2002

By _____
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Enclosures:

Certified Copies (2)
Petition and Fee for Extension of Time
Marked-Up Copy of Claims
Marked-Up Copy of Drawing

MARKED-UP COPY OF AMENDED CLAIMS

1. (Twice amended) An introducer for positioning an expandable endovascular prosthesis in a lumen of a patient, the prosthesis having a proximal portion and a distal portion, the introducer comprising:

a prosthesis positioning mechanism selectively releasable from the prosthesis when the prosthesis is positioned at a desired site in the lumen of a patient;

a first control member separable from the prosthesis positioning mechanism, retaining the prosthesis positioning mechanism with the proximal portion of the prosthesis, and controlling at least the longitudinal position of the proximal portion of the prosthesis; and

a second control member controlling at least the longitudinal position of the distal portion of the prosthesis.

4. (Twice amended) The introducer according to claim 2 [or 3], wherein said proximal attachment region includes a proximal attachment device.

8. (Twice amended) The introducer according to any one of claims 1 through 4 [7], wherein the introducer further comprises an expansion control mechanism controlling expansion of the prosthesis when the prosthesis is positioned at the desired site in the lumen of the patient.

9. (Twice amended) An endovascular arrangement for positioning an expandable prosthesis at a desired location in a lumen of a patient, said arrangement comprising a control section to be maintained external to the patient, and a prosthesis positioning mechanism controllable by the control section for moving and manipulating the prosthesis to a desired location in the lumen, wherein a first member extends from the control section to a proximal region of the positioning mechanism and controls the longitudinal and rotational position of the proximal region of the positioning mechanism, the proximal region of the positioning

mechanism having means for controlling the proximal end of the prosthesis, wherein a second member extends from the control section to a distal region of the positioning mechanism and independent of the first member controls the longitudinal and rotation position of the distal region of the positioning mechanism, the distal region having means for controlling the distal end of the prosthesis in cooperation with the second member.

18. (Twice amended) The arrangement according to any one of claims 9 through 11 [17], wherein the second member has means for controlling the distal end of the stent [whilst the latter is] inside the tubular means.

19. (Twice amended) The arrangement according to any one of claims 9 through 11 [18], wherein the arrangement further comprises release mechanisms in the control section for controlling wires extending to respective stents of the prosthesis.

20. (Twice amended) The arrangement according to any one of claims 9 through 11 [19], wherein the prosthesis positioning mechanism comprises a control arrangement for controlling the length of the prosthesis.

21. (Twice amended) The arrangement according to any one of claims 9 through 11 [19], wherein the prosthesis positioning mechanism comprises a rotational arrangement by which the relative angular orientation of the proximal and distal portions of the prosthesis can be adjusted.

22. (Twice amended) The arrangement according to any one of claims 9 through 11 [19], wherein the prosthesis positioning mechanism comprises a rotational arrangement by which the angular orientation of the prosthesis can be adjusted.

23. (Twice amended) The arrangement according to any one of claims 9 through 11 [19], wherein the arrangement [introducer] further comprises an expansion

control mechanism for controlling expansion of the prosthesis when the prosthesis is positioned at the desired site in the lumen of the patient.

Amend Claim 24 as follows:

24. (Amended) An introducer adapted for the introduction of a self expanding endovascular prosthesis into a lumen of a patient, the prosthesis having a proximal end and a distal end, the introducer comprising.

a. a proximal attachment device adapted to be attached to the proximal end of the prosthesis,

b. distal attachment device adapted to be attached to the distal end of the prosthesis,

c. each of the proximal and distal attachment devices attaching to the prosthesis in such a manner that the prosthesis can be held in tension therebetween and that each end of the prosthesis can individually be moved in proximal and distal directions and be rotated <u>independent of the other</u>, and

d. proximal releasing means associated with <u>and separable from</u> the proximal attachment device and distal releasing means associated with <u>and separable from</u> the distal attachment device to enable selective releasing of the proximal and distal ends of the prosthesis.

27. (Twice amended) An introducer as in claim 26 wherein the <u>flexible</u> thin walled [metal] tube includes fluid connection means external of the patient to enable the introduction of a medical reagent therethrough.

28. (Twice amended) An introducer as in claim 27 wherein the long flexible extension includes a hollow tube therethrough in fluid communication with the <u>flexible</u> thin walled [metal] tube and a plurality of side holes to enable dispersion of the medical reagent proximal of the prosthesis.

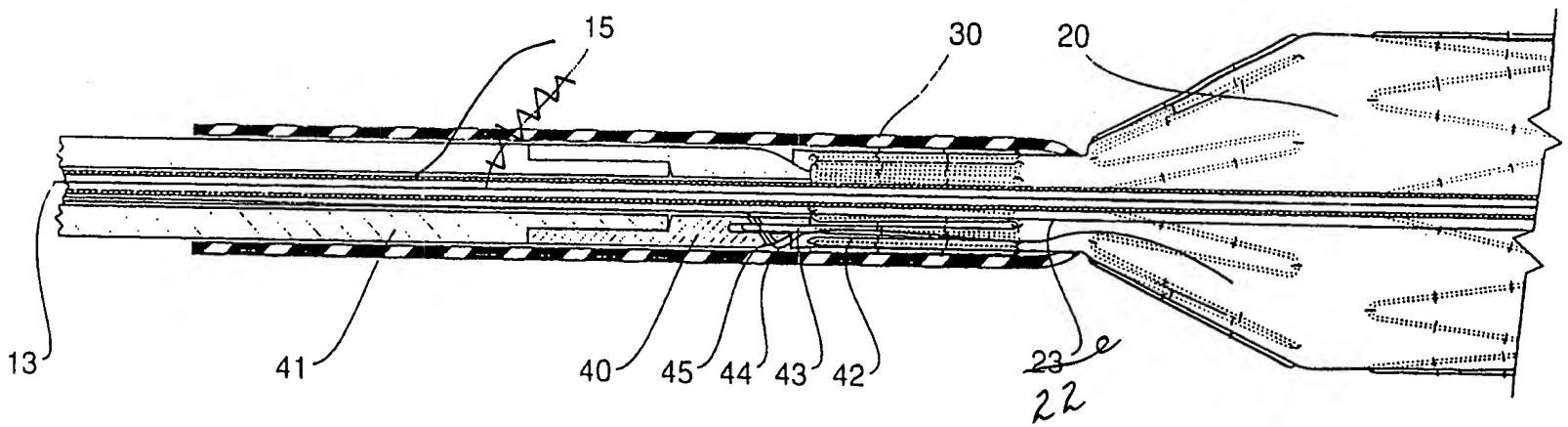

FIG 8

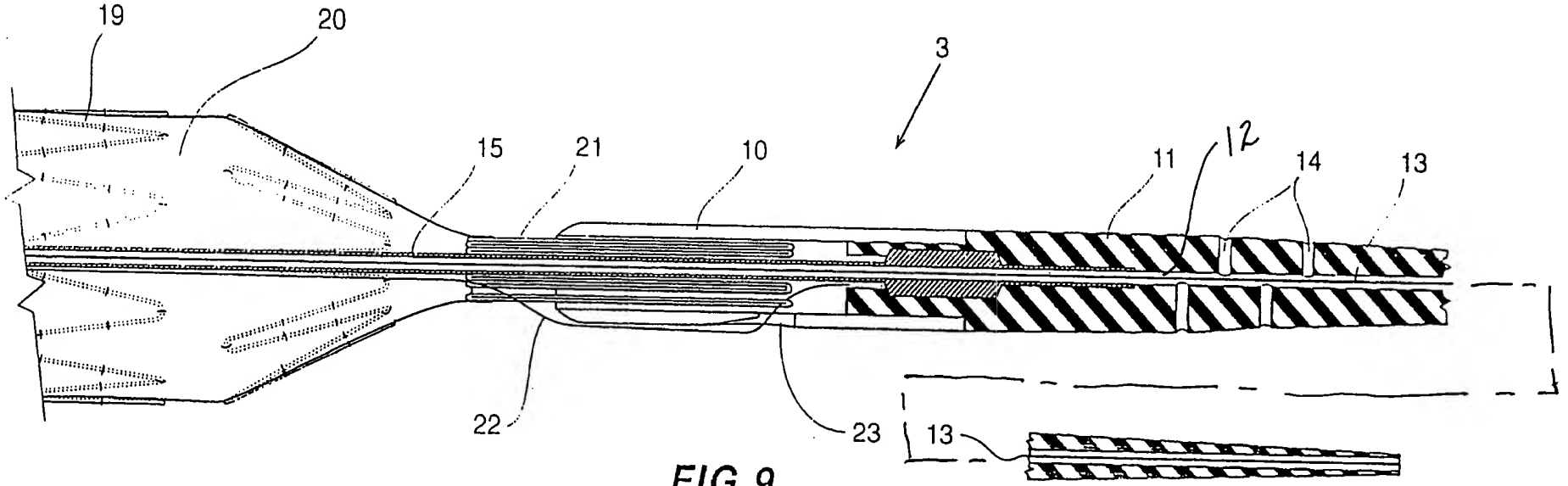

FIG 9